ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42054A; FRL-3431-6]

Termination of Rulemaking for Certain Chemicals in the Anilines Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of termination of rulemaking.

SUMMARY: This notice announces EPA's decision to terminate rulemaking for certain members of the anilines category (aniline, and chloro-, bromo-, and/or nitro-anilines) designated by the Interagency Testing Committee (ITC) for priority testing. EPA, at this time, is terminating rulemaking proceedings for health effects testing of 13 member chemical substances ("chemicals") because there is no basis for a finding that any of these chemicals may present an unreasonable risk of injury to human health and because there is no substantial or significant human exposure to these chemicals. EPA is terminating rulemaking for environmental effects testing of 17 member chemicals because there is no basis for a finding that the chemicals may present an unreasonable risk of injury to the environment, because there is no substantial release to the environment of these chemicals, or because adequate data are available. However, elsewhere in this issue of the **Federal Register**, EPA is announcing that eight additional category members are being tested for health and/or environmental effects, under Testing Consent Orders.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. EB-44, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 3, 1984 (49 FR 108), EPA issued an Advance Notice of Proposed Rulemaking under section 4(a) of TSCA to obtain data to help determine the potential risk of the anilines category to human health and the environment. The Agency is now issuing a decision not to require testing of 13 category members for health effects testing and 17 category members for environmental effects testing.

I. Background

Section 4(a) of TSCA authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data necessary to determine the risk chemicals present to human health and the environment. Section 4(e) of TSCA established the Interagency Testing Committee (ITC) to recommend chemicals to the Administrator of EPA for consideration for test rules under section 4(a).

In the ITC's Fourth Report to the Administrator, published in the **Federal Register** of June 1, 1979 (44 FR 31866), the Committee designated the anilines category for consideration of human health and environmental effects testing. The ITC defined the anilines category as: "Aniline and aniline substituted in one or more positions with a chloro, bromo, or nitro group or any combination of one or more of these substituent groups."

The ITC listed 19 chemicals in the category but instructed that the category not be limited to the 19 listed. EPA identified 20 chemicals within the ITC's category definition that were in production in 1982.

The ITC recommended human health and environmental effects testing in general because the high production volumes of category members suggested a potential for significant human exposure and environmental release. The ITC recommended testing for chronic health effects with emphasis on blood and nervous system disorders because most category members probably have the ability to induce methemoglobinemia and because humans are particularly sensitive to compounds that induce methemoglobinemia. The ITC recommended testing for teratogenicity because sustained methemoglobinemia may have adverse effects on the fetus and embryo of exposed pregnant women. The ITC recommended testing for carcinogenicity because aniline has been reported to be carcinogenic in male rats and other category members have a high suspicion of carcinogenicity. The ITC recommended testing for mutagenic effects because some members have been reported to be mutagenic and these results raise a suspicion for untested members. The ITC also recommended epidemiology studies to assess the possible adverse, chronic health effects, where there is or has been significant human exposure, because there is no information on the chronic effects produced in humans exposed to members of the category.

The ITC recommended environmental effects testing because occurrences of residues and persistence in soil and water for some category members suggested a continuous and highly dispersive discharge into the environment and available data raised a concern for the ability of members to produce adverse environmental effects. The ITC recommended chemical fate testing because of suspected environmental effects and because there are conflicting reports of the ability of animals, plants, and microbes to metabolize and tolerate these chemicals.

EPA's response to this designation was published in the **Federal Register** of January 3, 1984 (49 FR 108) as an Advance Notice of Proposed Rulemaking (ANPR) for the anilines category. In the ANPR, EPA: (1) Identified 20 individual chemicals in production in 1982, (2) presented a profile of the available health and environmental effects information on the chemicals, (3) indicated tentative gaps in the available health and environmental effects information, and (4) proposed for public comment an approach by which tests would be performed on category members chosen to represent small groups (subgroups) of category members instead of considering testing all category members. The ANPR named six subcategories (aniline, monochloroanilines, polychloroanilines, mononitroanilines, polynitroanilines, and halonitroanilines) and seven representative subcategory members (aniline; 4-chloroaniline; 3,4-dichloroaniline; 4-nitroaniline; 2,4-dinitroaniline; 2-chloro-4-nitroaniline; and 2-bromo-4,6-dinitroaniline) for possible health and environmental effects testing consideration.

II. Public Response to ANPR

EPA received comments and information from the Aniline Association (AA) and the Substituted Anilines Task Force (SATF) of the Synthetic Organic Chemical Manufacturers Association, and comments from Sodyeco Inc., Eastman Kodak, and the Upjohn Company (Refs. 1 through 5). The AA and SATF provided results of surveys of processors and users to determine the potential for human exposure and environmental release. The AA and SATF also provided additional data from manufacturers and processors on biological and workplace monitoring for human worker exposure. The exposure, release, and monitoring data were supplied by the SATF as confidential business information. The summary conclusions of the SATF and other comments were that: (1) The available data on potential human exposure, environmental release, and health and environmental effects of aniline and

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substituted anilines would support neither a TSCA section 4(a)(1)(A) nor a section 4(a)(1)(B) finding to require further testing of anilines category members and, (2) the proposed testing will have such an adverse economic impact as to force the manufacturers of the dyes and pigments made from these intermediates to stop production in the United States. Industry toxicologists for the SATF commented that the substituted anilines should not be considered a single category for purposes of determining the need to test because the category members share no common health effect, and the category should include only those members for which a section 4(a) finding could be made. The SATF commented that structural and biological similarities among the members of three chemical groups—nitroanilines, chloroanilines, and halonitroanilines—may be sufficient to permit the selection of a representative test substance, the toxicity of which might be used to characterize other members of the group.

III. Decision Not To Continue Rulemaking

A. Environmental Effects

EPA has decided at this time not to continue rulemaking proceedings to require chemical fate or environmental effects testing of the 17 anilines category members listed in the following Table 1:

TABLE 1.—ANILINES CATEGORY MEMBERS DROPPED FROM CHEMICAL FATE OR ENVIRONMENTAL EFFECTS TESTING

CAS No.	Chemical name	Reason for dropping
106-42-9	3-Chloroaniline	(1)
106-47-8	4-Chloroaniline	(1)
608-27-5	2,3-Dichloroaniline	(1)
554-00-7	2,4-Dichloroaniline	(1)
95-82-9	2,5-Dichloroaniline	(1)
95-76-1	3,4-Dichloroaniline	(1)
634-93-5	2,4,6-Trichloroaniline	(1)
88-74-4	2-Nitroaniline	(1)
99-09-2	3-Nitroaniline	(1)
100-01-6	4-Nitroaniline	(1)
97-02-9	2,4-Dinitroaniline	(1)
121-87-9	2-Chloro-4-nitroaniline	(2)
6283-25-6	2-Chloro-5-nitroaniline	(1)
89-63-4	4-Chloro-2-nitroaniline	(1)
635-22-3	4-Chloro-3-nitroaniline	(1)
827-94-1	2,6-Dibromo-4-nitroaniline	(1)
1817-73-8	2-Bromo-4,6-dinitroaniline	(1)

[1] Little or no production and release.
[2] Using available data, EPA finds no indication of potential unreasonable risk.
[3] Data are adequate to reasonably determine or predict the potential for risk of injury to the environment.

Thirteen category members are not being proposed for testing at this time, because there is little or no production or importation of some of the compounds, and because the reported environmental release is judged to be insignificant for all 13 chemicals.

Because there is some manufacture and release of 4-chloroaniline, 3,4-dichloroaniline, 2-nitroaniline, and 4-nitroaniline, EPA has estimated the environmental risk potential of these chemicals, by comparing available aquatic vertebrate or invertebrate LC50's to site-specific predicted environmental concentrations (PECs) (Refs. 6 through 14). In general, if the median lethal concentration (LC50) for a chemical exceeds its predicted or measured environmental concentration by 3 orders of magnitude or exceeds 1 mg/L and the potential for the substance to bioconcentrate in tissues of aquatic organisms is low, i.e. Kow < 100, the Agency considers the substance to be of low priority for further aquatic toxicity testing or assessment. The factor of 3 orders of magnitude between the LC50 and PEC takes into account uncertainties related to interspecies variability and acute-to-chronic or lab-to-field effects extrapolations. Because the LC50's for 4-chloroaniline, 3,4-dichloroaniline, 2-nitroaniline, and 4-nitroaniline exceed the site-specific PECs for these category members by 3 orders of magnitude, or exceed 1 mg/L and the Kow values of these anilines are <100, EPA finds no indication of potential unreasonable risk. Furthermore, EPA believes that factors used in calculating the predicted environmental concentrations, such as assuming low flow conditions of a river and assuming that no biodegradation or adsorption occurs to remove these chemicals from the aquatic environment, are very conservative and provide an additional margin of confidence that current releases of these four category members present no unreasonable risk of injury to the environment. In addition, EPA finds that data on the environmental effects of 3,4-dichloroaniline are sufficient to reasonably determine or predict the potential for risk of injury to the environment (Refs. 7 through 10).

In summary, the ITC recommended chemical fate and environmental effects testing of the anilines category because high production volumes of some members suggested a potential for significant environmental exposure and a concern for potential persistence in soil and water and for members to produce adverse environmental effects. However, EPA concludes that available environmental effects data and confidential release data provided by manufacturers and processors of these substances do not support a TSCA section 4(a)(1)(A) finding that the anilines category members listed in Table 1 may present an unreasonable risk of injury to the environment. EPA also concludes on the basis of this information, some of which was unavailable to the ITC, that there is not sufficient environmental release to support a TSCA section 4(a)(1)(B) finding of substantial production and substantial release to the environment. Therefore, the Agency is not proposing chemical fate or environmental effects testing of the anilines category members, listed in Table 1, at this time.

EPA will monitor future manufacturing of these 17 chemicals through the section 8(b) TSCA Inventory Update Rule, 40 CFR 710, published in the **Federal Register** of June 12, 1986 (51 FR 21438), because some of the anilines category members for which testing is not being required cause toxic effects in aquatic organisms.

B. Health Effects

EPA has decided at this time not to continue rulemaking proceedings to require human health effects testing of the 13 anilines category members listed in the following Table 2:

TABLE 2.—ANILINES CATEGORY MEMBERS DROPPED FROM HEALTH EFFECTS TESTING

CAS No.	Chemical name
106-42-9	3-Chloroaniline
608-27-5	2,3-Dichloroaniline
554-00-7	2,4-Dichloroaniline
95-82-9	2,5-Dichloroaniline
634-93-5	2,4,6-Trichloroaniline
99-09-2	3-Nitroaniline
121-87-9	2-Chloro-4-nitroaniline
6283-25-6	2-Chloro-5-nitroaniline
89-63-4	4-Chloro-2-nitroaniline
635-22-3	4-Chloro-3-nitroaniline
99-30-9	2,6-Dichloro-4-nitroaniline
827-94-1	Dibromo-4-nitroaniline
1817-73-8	2-Bromo-4,6-dinitroaniline

EPA has assessed the potential risk of injury to human health from exposure to chemicals in the anilines category, and EPA's evaluation indicates that a TSCA section 4(a)(1)(A) finding of "may present an unreasonable risk" cannot be supported for these 13 chemicals (Refs. 14 through 23).

The ITC based its recommendations for chronic health effects (with emphasis on blood and nervous system disorders) and teratogenic effects testing and for epidemiology studies of the anilines category on the potential for some category members to cause methemoglobinemia in humans. The ITC recommended mutagenic and oncogenic

effects testing because some category members were reported to be oncogenic and/or mutagenic and these results raise a suspicion of these effects for untested members.

On the basis of information not available to the ITC on the number of workers potentially exposed, duration of potential exposure, and measured or estimated exposure levels. EPA has determined that there is no basis, at this time, to believe that these 13 chemicals may present an unreasonable risk for any of the effects recommended by the ITC because: (1) Very few workers are potentially exposed and the period for potential exposure is brief, (2) available health effects data for the anilines category members, listed in Table 2, report no chronic (including hematologic and neurotoxic), teratologic, or reproductive effects that occur below exposure levels that cause methemoglobinemia (concern for reporductive effects was raised by EPA in the ANPR), and (3) the manufacturers and processors control human exposure below the threshold for methemoglobinemia (and therefore for known chronic, teratologic, and reproductive health effects of the anilines category) (Refs. 14 and 16). Epidemiology studies are not necessary at this time because reported worker exposure levels are below the concentrations that are likely to cause health effects from exposure to methemoglobinemia-producing compounds. In addition, EPA finds the data (currently available or required under an EPA Office of Pesticide Programs Registration Standard) on the chronic, teratologic, and reproductive effects of 2,6-dichloro-4-nitroaniline are sufficient to determine or predict the risk of injury to human health for these effects (Ref. 17).

In summary, the ITC recommended testing of anilines for chronic effects, and teratologic, oncogenic, and mutagenic effects, and EPA raised a possible concern for reproductive effects; however, EPA concludes that available health effects and confidential occupational exposure information provided by manufacturers and processors of substituted anilines, some of which was not available to the ITC, does not support a TSCA section 4(a)(1)(A) finding that the 13 category members, listed in Table 2, may present an unreasonable risk of injury to human health. EPA also concludes on the basis of this information that there is not sufficient human exposure to support a TSCA section 4(a)(1)(B) finding for health effects. Therefore, the Agency is not proposing health effects testing for the substituted anilines listed in Table 2 at this time.

EPA will monitor future manufacturing of these 13 chemicals through the section 8(a) TSCA Inventory Update Rule, 40 CFR Part 710, published in the **Federal Register** of June 12, 1986 (51 FR 21438), because some of the anilines category members for which testing is not being required cause toxic effects in laboratory animals.

IV. Public Record

EPA has established a public record for this decision not to test under section 4 of TSCA (docket number OPTS-42054A). This record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notice designating the Anilines category to the priority list (44 FR 107; June 1, 1979), and all comments received thereon.

(2) Advance Notice of Proposed Rulemaking for the Anilines Category (49 FR 108; January 3, 1984).

(3) Partial Update of TSCA Inventory Database; Production and Site Reports. Final Rule. (51 FR 21438; June 12, 1986).

(4) Communications consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(5) Reports—published and unpublished factual materials, including contractors' reports.

B. References

(1) LaRoe, Winn and Moerman, Counsel for Aniline Association. Comments of the Aniline Association on the Advance Notice of Proposed Rulemaking on the Need for Additional Testing of Aniline Under Section 4 of TSCA. (1984).

(2) Cleary, Gottlieb, Steen and Hamilton, Counsel for Substituted Anilines Task Force. Comments on Advance Notice of Proposed Rulemaking for Chloro-, Bromo-, and/or Nitroanilines, for the Substituted Anilines Task Force of Synthetic Organic Chemical Manufacturers Association. (1984).

(3) Sodyeco Inc. Comments of Sodyeco Inc. on the Advance Notice of Proposed Rulemaking on the Need for Additional Testing of Anilines Under Section 4 of TSCA. Letter of March 2, 1984 from B.W. Drum to TSCA Public Information Office.

(4) Eastman Kodak Company. Comments of Eastman Kodak on the Advance Notice of Proposed Rulemaking on the Need for Additional Testing of Aniline Under Section 4 of TSCA. Letter of March 2, 1984 from R.F. Brothers to TSCA Public Information Office.

(5) Upjohn Company. Aniline and Chloro-, Bromo- and/or Nitroanilines; Response to the Interagency Testing Committee by Upjohn Company. Letter of February 28, 1984 from J.S Mehring to TSCA Public Information Office.

(6) Monsanto Chemical Company. "Acute toxicity of 4-chloroaniline to *Daphnia magna*." Conducted by Analytical Biochemistry Laboratories. Unpublished company data. (1979).

(7) Adema, D.M. and Vink, G.J. "A comparative study of the toxicity of 1,1,2-trichloroethane, dieldrin, pentachlorophenol, and 3,4-dichloro-aniline for marine and freshwater organisms." *Chemosphere* 10: 533–554. (1981).

(8) Crossland, N.O. and Hillaby, J.M. "3,4-Dichloroaniline: Chronic toxicity to *Daphnia magna*." Shell Research Limited, Sittingbourne Research Center, Sittingbourne, Kent, England. Unpublished company data. (1983).

(9) Hillaby, J.M. and Crossland, N.O. "3,4-Dichloroaniline: Acute toxicity to *Daphnia magna* and *Selenastrum capricornutum*." Shell Research Limited, Sittingbourne Research Center, Sittingbourne, Kent, England. Unpublished company data. (1983).

(10) USEPA. U.S. Environmental Protection Agency. Testing results report of USEPA Environmental Research Laboratory, Duluth, MN. (1985).

(11) Schulz, T.W. and Applehans, F.M. "Correlations for the acute toxicity of multiple nitrogen substituted aromatic molecules." *Ecotoxicology and Environmental Safety* 10: 75–85. (1985).

(12) Monsanto Chemical Company. "Acute toxicity of 3,4-dichloroaniline to *Daphnia magna*." Conducted by Analytical Biochemistry Laboratories. Unpublished company data. (1979).

(13) USEPA. Predicted environmental concentrations for selected substituted anilines. Confidential Business Information, prepared by M. McCommas, Test Rules Development Branch, Office of Toxic Substances. (1985).

(14) Cleary, Gottlieb, Steen and Hamilton. Comments on Advance Notice of Proposed Rulemaking for Chloro-, Bromo-, and/or Nitroanilines (Appendix A. Confidential Business Information) for the Substituted Anilines Task Force of the Synthetic Organic Chemical Manufacturers Association. (1984).

(15) Reynolds, W.P., Roell, M.G. and Fleming, J.J. "Methemoglobin inducing potential of various substituted anilines in rats." Toxicology Section of Hoechst-Roussel Pharmaceuticals Incorporated) Somerville, NJ. Unpublished company data. (1984).

(16) OSHA. Occupational Safety and Health Administration. OHDS-4 Health Sampling Report for Aniline (Substance Code 0220) for Period June 1979 through May 1983. U.S. Department of Labor, Washington, DC. (1979).

(17) USEPA. Office of Pesticides Programs. Registration Standard for 2,6-Dichloro-4-nitroaniline. (1984).

(18) Donoghue, J.L. "Subchronic oral toxicology of 4-chlor-3-nitroaniline in the rat." Toxicological Sciences Health and Environmental Laboratories, Eastman Kodak Company, Rochester, NY. Unpublished company data. (1983).

(19) Chopade, H.M. and Matthews, H.B. "Disposition and metabolism of 4-chloro-2-nitroaniline in the male F344 rat." *Journal of Toxicology and Environmental Health* 12:267-282. (1983).

(20) Chopade, H.M. and Matthews, H.B. "Disposition and metabolism of 2-bromo-4, 6-

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dinitroaniline in the male F344 rat." *Journal of Toxicology and Environmental Health.* (1984).

(21) Weisburger, E.K., Russfield, A.B., Homburger, F. et al. "Testing of 21 environmental aromatic amines or derivatives for long term toxicity or carcinogenicity." *Journal of Environmental Pathology and Toxicology* 2:235-256. (1978).

(22) NIEHS. National Institute of Environmental Health Sciences. SMVCE report on 4-chloro-2-nitroaniline. Conducted by Litton Bionetics for N. Lamb, Environmental Health Research and Testing Laboratory, Durham, NC. (1984).

(23) NTP. Status of Chemicals in NTP Toxicological studies. (1985).

This record includes basic information considered by the Agency in developing this notice. Confidential business information (CBI), while part of the record, is not available for public review. A public version of the record from which CBI has been deleted is available for inspection in the TSCA Public Docket Office, Room, Rm. NE-G004, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement the record periodically with additional relevant information received.

Authority: 15 U.S.C. 2603.

Dated: August 8, 1988.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

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